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EXAMINER
SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/883,152	KENNEDY ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-59* is/are pending in the application.

4a) Of the above claim(s) *3-11, 14-20, 22-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *08 March 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12003* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *5 references on 892* .

DETAILED ACTION

Response to Applicant

This action is in response to Applicant's response to the restriction requirement, filed February 26, 2003. Applicant elected the claims of Group I, claims 1, 2, 12, 13, and 21, and the further prosecution of SEQ ID NO:3, without traverse. Subsequently, applicant filed an amendment on March 11, 2003 wherein; Claims 3-11, 14-20, and 22-42 have been withdrawn, claim 1, 2, 12, 13, and 21 have been canceled, and claims 43-59 have been added. Claims 43-59 are now pending and have basis in originally elected, now cancelled claims 1, 2, 12, 13, and 21.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The present application's claim to benefit of a U.S. provisional Application 60/211835 filed June 15, 2000, is granted.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code(Pg. 78, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

A. Claim 51 is objected to because the word "of" should be inserted after "level" in the second line of the claim in order for the claim to make sense. Additionally, Claim 51 needs to

have a colon inserted after "steps" in the first line of the claim to delineate the preamble from the body of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 43-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

Nature of the invention. Claims 43-59 are broadly drawn to a method for detecting a cancerous cell comprising detecting a level of a nucleic acid gene product in a test sample obtained from a cell of a subject, wherein said gene is identified by the sequence of SEQ ID NO:3, or complement thereof; and comparing the level of said nucleic acid gene product to a control level of said nucleic acid gene product. The specification does not at all enable correlating the level of

SEQ ID NO: 3 with the detection of a colon cancer cell or cancerous cell generally. The specification does not specify any examples of such well-established, *in–vitro* model systems, practiced methods or evidence for the ability of the detected expression of SEQ ID NO:3 to be correlated with the presence of any sort of cancerous cell. The examples that are taught in the specification include polynucleotides that correspond to genes differentially expressed in colon tissue from a **single** patient(Table 3). Table 3 teaches that Cluster 9083, including SEQ ID NO:3, as well as many other partial mRNA transcripts, is over-expressed ten times in Tumor(lib16) clones and 14 times greater in High Met(lib17) clones than in the normal (lib 15) clones. The table does not teach that SEQ ID NO:3 **alone** is over-expressed consistently in an adequate sample size representing more than just a single, isolated patient. Table 4 of the specification teaches the cluster 9083, including SEQ ID NO: 3 as well as many other partial mRNA transcripts to have a "strong" similarity to Ankyrin repeats. The specification does not teach which specific partial mRNA transcript in the cluster actually shares the similarity nor does the specification teach the relevance that such similarity has to the detection of any sort of cancerous cell. In example 4, page 84, the specification teaches that cluster 9083(SK2) is over-expressed in 3 out of 4 patients, designated as "UC#1, UC#2, UC#4, and UC#7." However, the specification omits an explanation of to what each "UC#" designation corresponds. In Table 1, UC#2 is defined as both a normal colon and tumor colon cDNA library, it is therefore not clear to which cDNA library Example 4 is referring. In addition, the table does not make reference to any of UC #1, 4, or 7. Furthermore, although Table 1 reveals SEQ ID NO:3, cluster 9083, and SK2 in the same row of the table, the specification omits any explanation of how each entity is related to one another and as a result, the specification does not teach the relevance of the

Example 4 results with respect to SEQ ID NO:3. Tables 5 and 6 totally omit any teaching of SEQ ID NO: 3 and correlating its level of expression with the detection of a colon cancer cell or cancerous cells generally. It is highly unpredictable to extrapolate findings from any of the specification's teaching to a method for detecting a cancerous cell comprising detecting a level of a nucleic acid gene product in a test sample obtained from a cell of a subject, wherein said gene is identified by the sequence of SEQ ID NO:3, or complement thereof; and comparing the level of said nucleic acid gene product to a control level of said nucleic acid gene product. It is important to note that even if applicant would enable the detection of cluster 9083 in cancerous cells, the same detection of SEQ ID NO: 3 would not be enabled for determining cancerous cells. Furthermore, while even if the method's step of identifying that SEQ ID NO: 3 is over expressed in cancerous cells, which characterizes the "how to make" portion of the enablement requirement, is enabled, the specification still omits teachings to enable the "how to use portion" as any teachings of how to use the discovered over-expressed SEQ ID NO:3 once it has been discovered. of identifying a genotype would include the "how to make" portion of the enablement requirement, it still omits the "how to use portion" as the specification omits any teaching of how to use the discovered genotype once it has been discovered.

With respect to claims 46, 51-55 directed to the same method as above, but to specifically the detection of colon cancer cells from colon tissue. The lack of teachings as recited above, as well as those specific to colon cells add to the unpredictability of the present research project, method.

With respect to claims 56-59 drawn to a method for assessing tumor burden by the detection of an over-expressed SEQ ID NO:3 in a colon tissue sample. The specification does not teach what characterizes tumor burden, and in addition to not teaching the overexpression of SEQ ID NO:3

as stated supra, does not teach how an over-expression of SEQ ID NO:3 would relate to tumor burden. As a result, once again, neither prong of the enablement requirement is taught by the specification. The nature of this invention is quite unpredictable because it requires a reliance on the prophetic testimony by applicant that the detection of a larger, nebulously defined group, including SEQ ID NO:3, cluster 9083, enables the above methods for detecting cancerous cells or colon cancer cells through the detection of SEQ ID NO:3. In the same way, the method for assessing tumor burden remains not enabled.

Scope of the invention. The scope of the invention is very broad, claiming methods for detecting any cancerous cell comprising a method of detecting any level of any nucleic acid gene product identified by SEQ ID NO:3 and comparing the detected levels to that of a control level of the gene product. Much unpredictability exists in the broad claiming of this method including such general limitations as "detecting a level" and comparing this level to a "control level". Furthermore, as alluded to in the Nature of the invention, even if applicants would enable detection of an over-expressed SEQ ID NO:3, they would still be required to enable the connection to colon cancer and the ability to asses tumor burden.

State of the art. The prior art does not disclose a method for detecting a cancerous cell comprising detecting a level of a nucleic acid gene product in a test sample obtained from a cell of a subject, wherein said gene is identified by the sequence of SEQ ID NO:3, or complement thereof; and comparing the level of said nucleic acid gene product to a control level of said nucleic acid gene product, thus the invention appears to be novel in terms of the prior art. However, the lack of support from the prior art in the reliability of extrapolating data from a detection involving a single patient to reflect a general trend for all detection(As seen in Table 3)

and the prior art's lack of support for results that have been obtained through cell lines to necessarily reflect the same results that would occur in vivo(Table 1) results in the invention being unpredictable in terms of its use as presently claimed. First, with respect to the use of a single patient's data as proof of a general trend, the art teaches that a large sample size representing a variation of constituents is required for obtaining accurate results. Falzarano et al teach a method of screening for colon cancer in which, "utilizing the large sample size" was an important component in their study's objectives(Hawaii Med J., 2002). In addition, the National Cancer Institute teaches that "a trial designed to correct for or eliminate selection and other biases... would require a large sample size"(Cancer Prevention, 2002). Furthermore, with respect to the extrapolation of data from cell lines, it is well accepted that the genetic alterations which occur in cell lines are not necessarily reflective of the genetic changes which occur in vivo (see, for example, Dermer et al (BioTechnology (1994) 12: 320). Both, the use of a single patient to determine a general trend and the extrapolation of data obtained from cell lines to in-vivo approaches, makes drawing conclusions about the present data highly unpredictable.

Number of working examples and Guidance provided by applicant. The instant specification only provides guidance and working examples concerning single patient studies, entire clusters of data, cell lines, cDNA libraries of unknown origin and SEQ ID NOS. Considering the unpredictability surrounding the extrapolation of data from experiments using such different compositions as a cluster of many partial mRNA transcripts, individual mRNA transcripts, cDNA libraries, and single sample studies, as pointed out in the Nature of the invention section of this rejection, the skilled artisan would have to practice undue and unpredictable trial and error experimentation in order to practice the invention by detecting the

expression level of SEQ ID NO:3. In addition, considering the lack of working examples showing the association between a particular expression level of SEQ ID NO:3 alone and any type of cancerous cell, even more unpredictability exists.

Level of skill in the art. The level of skill involved in relating characteristics of such different molecules and compositions(cluster 9083, cDNA libraries and SEQ ID NO:3 etc) to each other is very high if not impossible. Additionally, the functional use of such assumed similar properties from such different molecules is seen, in this instance, to be prophetic.

Unpredictability of the art. There are examples of why the study parameters used in the present application can lead to great unpredictability in the art as illustrated in the State of the Art section. Both the prior art and the instant specification are deficient in terms of teaching the applicability of cluster data and data relying soley upon a single patient to that ofSEQ ID NO:3 expression. Furthermore, the lack of teachings of how to use the expression or putative over-expression of SEQ ID NO:3 to identify cancerous cells, colon cancer cells or to asses tumor burden all contribute to the great unpredictability involved in making and using this invention. In light of these deficiencies, the skilled artisan would be forced to practice undue and unpredictable trial and error experimentation when practicing the instant invention.

Considering the Nature of the invention, the guidance provided by both the prior art and the instant specification, and the broad scope of the invention, it is clear that the skilled artisan would be required to practice undue and unpredictable trial and error experimentation to practice the invention that is claimed.

35 U.S.C. 112, Written Description Rejection

2. Claims 51-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

The specification discloses SEQ ID NO:3 which corresponds to a partial mRNA transcript containing an open reading frame that "corresponds" to genes differentially expressed in colon cancer patient tissue and that is also contained in a cluster, 9083, having a strong similarity to Ankyrin repeats. Claims 51-55, are directed to encompass sequences comprising at least 50 and at least 100 contiguous nucleotides of SEQ ID NO:3 capable of hybridizing as a probe to a target. A review of the language of the claims indicates that the claims are drawn to a genus, i.e., any nucleic acid that minimally contains these aforementioned sequences in addition to any full length gene which contains the sequence, any splice variants, or cDNAs. A review of the full content of the specification indicates that the sequence of nucleotides of SEQ ID NO: 3 and all aforementioned variations, capable of hybridization, are essential to the operation and function of the claimed invention. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more

than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The named ORF is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for isolating and characterizing cDNA sequences from *E. grandis*, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe *E. grandis* cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the specification does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute *E. grandis* cDNA appears in the application. Accordingly, the specification does not provide a written description of the invention of claims 1, 4, and 6-15.

Therefore, none of the sequences encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. The present claims encompass full-length genes, splice variants, and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of claims 51-55 because a polynucleotide probe comprising at least 50 or 100 nucleotides of SEQ ID NO: 3 encompass a great deal more than just the enumerated sequence listed. The specification has not described molecules that contain variations in SEQ ID NO:3, which are encompassed by the claims. For example, the specification does not define the nucleotides flanking the 50 or 100 mer fragments of SEQ ID NO:3. Furthermore, the specification omits teachings of all molecules containing only 50 to 100 nucleotides of SEQ ID NO:3 that may have very diverse functions and whose expression would not necessarily be associated with the occurrence of cancer. Therefore the specification has not taught a representative number of molecules comprising 50-100 nucleotides of SEQ ID NO:3 whose expression is associated with cancer. The specification describes SEQ ID NO:3 as representing a partial mRNA transcript containing an open reading frame that "corresponds" to genes(SK2?) differentially expressed in colon cancer patient tissue and that is also contained in a cluster, 9083, having a strong similarity to Ankyrin repeats. The specification contains no description of the DNA which lie 5' or 3' of the nucleotides of SEQ ID NO:3. The specification

does not teach how SEQ ID NO:3 "corresponds" to a full length gene over-expressed in colon cancer tissue, whether the sequence is surrounded by coding sequence, intronic sequence, a non-coding sequence, or a regulatory sequence for example. The claims are written such that they encompass all aforementioned variants as well as genomic sequences of any length which minimally contain at least 50 or 100 contiguous nucleotides of SEQ ID NOS: 3 and could include genes and/or regulatory domains which have not been described and of which applicant does not appear to have been in possession.

Weighing all factors, 1) partial structure of the DNAs that comprise at least 50 or 100 contiguous nucleotides of SEQ ID NO: 3(Claims 51 and 55) or complements thereof, 2) the breadth of the claim as reading on genes yet to be discovered in addition to numerous splice variants and cDNAs, 3) the lack of correlation between the structure and the function of the genes and/or splice variants; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise at least 50 or 100 contiguous nucleotides of SEQ ID NO: 3 or complements thereof.

35 U.S.C. 112 2nd ¶

3. Claims 43-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 43-50 are indefinite over the recitation of "said gene." The phrase lacks antecedent basis as claim 1 recites a "nucleic acid gene product" but makes no prior reference to

a gene or the gene to which "said gene" refers. It is therefore unclear which gene is identified by the sequence of SEQ ID NO:3 and appropriate correction is required.

B. Claims 43-50 are further indefinite as it is not clear whether the method is one for detecting a cancerous cell or for comparing the level of nucleic acids. The preamble of claim 43 recites a step for detecting a cancerous cell but no final process step reciting that any correlation is ever made between the level of nucleic acids and the detection of a cancerous cell.

C. Claims 48 and 49 are indefinite as it is unclear if "uses polymerase chain reaction" and "uses hybridization" are intended to further limit claims 48 and 49 respectively and if these phrases should be given any weight as they are not actual process steps.

D. Claim 56-59 are indefinite over the recitation of "tumor burden." This phrase makes the claims unclear because the specification does not define what is encompassed by "tumor burden", and only mentions it briefly as an aside on page 57. There is no fixed definition in the art for what constitutes tumor burden. It is unclear, eg. whether the term refers to how severe a tumor is, ie how much burden it is placing on an effected individual, or the burden on a unaffected individual that they will experience future tumors. The claims should be amended to clarify to what specific condition "tumor burden" refers.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 51-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Quackenbush et al.(NCBI Database, 6/1/2000)

It should be noted that Claim 51-55's recitation of "comparing" is a mental step and as such is not given weight and as a result are anticipated by Quackenbush et al. as the same step of

detecting the level of gene expression of a nucleic acid comprising 50 and 100 nucleotides of SEQ ID NO:3 method is taught.

The reference teaches a method of assessing gene expression patterns in a model of colon tumor metastasis using a 19,200 element cDNA microarray. Inherent in the microarray analysis are steps of hybridizing probe and detecting gene products in addition to the steps of comparing the test samples to those of a control. Specifically the reference teaches the detection of at least 50 or 100 contiguous nucleotides of SEQ ID NO:3 in its 561 bp cDNA sequence with accession number AW965860(see attached alignment and reference).

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

4/21/2003

CARLA J. MYERS
PRIMARY EXAMINER